DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 1, 2014

Shenzhen Mindray Biomedical Electronics Co. Ltd
Yanhong Bai
Manager Regulatory Affairs
Mindray Building, Keji 12th Road South, High-tech Industrial Park
Nanshan, Shenzhen, 518057 CH

Re: K132662
Trade/Device Name: Passport Series Patient Monitors
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II
Product Code: MHX, DSI, MLD, DRT, DXN, DSK, FLL, DQA, DPZ, CCK, CBQ, CBS, CBR, CCL, DXG
Dated: July 8, 2014
Received: July 9, 2014

Dear Yanhong Bai,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

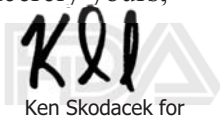
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Ken Skodacek for
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132662

Device Name: Passport Series patient monitors

Indications for Use:

The Passport Series Patient Monitors, including Passport 8 and Passport 12, are intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG (3-lead, or 5-lead, or 12-lead selectable), arrhythmia detection and ST Segment analysis, heart rate (HR), respiration (Resp), temperature (Temp), pulse oxygen saturation (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), cardiac output (C.O.), carbon dioxide (CO2), and anesthetic gas (AG).

All the parameters can be applied to single adult, pediatric and neonatal patients with the exception of the following:

- C.O. monitoring is restricted to adult patients only;
- PAWP monitoring is not intended for neonatal patients;
- The Mortara ECG Algorithm arrhythmia detection and ST Segment analysis is intended for adult and pediatric patients. The Mindray ECG Algorithm arrhythmia detection is intended for adult and pediatric patients, and the Mindray ECG Algorithm ST Segment analysis is intended for adult patients only.
- 12-lead monitoring and AG monitoring are available for Passport 12 Patient Monitors only.

The monitors are to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians.

Prescription Use X **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ken Skodacek for
Bram Zuckerman

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

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Date Prepared: July 7, 2014

Trade/Proprietary Name: Passport Series Patient Monitors (including Passport 8 and Passport 12)

Common Name: Patient Monitor

Classification:

21 CFR 870.1025	Detector and alarm, arrhythmia (DSI)	Class II
21 CFR 870.1025	Monitor, physiological, patient (with arrhythmia detection or alarms) (MHX)	Class II
21 CFR 870.1025	Monitor, ST Segment with Alarm (MLD)	Class II
21 CFR 870.2300	Monitor, cardiac (incl. cardiotachometer & rate alarm) (DRT)	Class II
21 CFR 870.1130	System, Measurement, Blood-Pressure, Non-Invasive (DXN)	Class II
21 CFR 870.1110	Computer, Blood-Pressure (DSK)	Class II
21 CFR 880.2910	Thermometer, Electronic, Clinical (FLL)	Class II
21 CFR 870.2700	Oximeter (DQA)	Class II
21 CFR 870.2710	Oximeter, Ear (DPZ)	Class II
21 CFR 868.1400	Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase (CCK)	Class II
21 CFR 868.1500	Analyzer, Gas, Enflurane, Gaseous-Phase (Anesthetic Concentration) (CBQ)	Class II
21 CFR 868.1620	Analyzer, Gas, Halothane, Gaseous-Phase (Anesthetic Conc.) (CBS)	Class II
21 CFR 868.1700	Analyzer, Gas, Nitrous-Oxide, Gaseous Phase (Anesthetic Conc.) (CBR)	Class II

21 CFR 868.1720	Analyzer, Gas, Oxygen, Gaseous-Phase (CCL)	Class II
21 CFR 870.1435	Computer, Diagnostic, Pre-Programmed, Single-Function (DXG)	Class II

Legally Marketed Predicate Devices:

K092449 BeneView T Series patient monitors (Including Models BeneView T8, BeneView T6 andBeneView T5), Shenzhen Mindray Bio-medical Electronics Co., LTD

K123074 IMEC, IPM AND BENEVIEW T1 PATIENT MONITORS, Shenzhen Mindray Bio-medical Electronics Co., LTD

Device Description:

The Passport Series Patient Monitors (including Passport 8, Passport 12) are the developed new series based on the technical platform of the iPM Series patient monitors.

Comparing with the cleared iPM Series Patient Monitors, the WiFi function is added on the subject patient monitors.

Indication for Use:

The Passport Series Patient Monitors, including Passport 8 and Passport 12, are intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG (3-lead, or 5-lead, or 12-lead selectable), arrhythmia detection and ST Segment analysis, heart rate (HR), respiration (Resp), temperature (Temp), pulse oxygen saturation (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), cardiac output (C.O.), carbon dioxide (CO2), and anesthetic gas (AG).

All the parameters can be applied to single adult, pediatric and neonatal patients with the exception of the following:

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- 12-lead monitoring and AG monitoring are available for Passport 12 Patient Monitors only.

The monitors are to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians.

Technology:

For the parameters (including ECG, arrhythmia detection, ST Segment analysis, HR, RESP, TEMP, SpO2, PR, NIBP, IBP, C.O., CO2 and AG), the subject devices are totally same with the predicate devices iPM Series patient monitors (K123074).

For the WiFi function, the subject devices are substantially equivalent to the Predicate devices BeneView T Series Patient monitors (K092449).

Test Summary:

The Passport Series Patient Monitors (including Passport 8, Passport 12) comply with the recognized safety, performance and electromagnetic compatibility standards. A risk analysis has been developed to identify potential hazards and document the mitigation of the hazards. Mindray's product development process required that the following activities be completed during the development of the patient monitors:

Requirements specification review
Hardware and Software testing
Code design and code reviews
Environmental EMC testing
Safety testing
Performance testing
Hardware and Software validation

Conclusion:

The results of all testing demonstrate that the Passport Series Patient Monitors are as safe, as effective, and perform as well as the predicate devices.